REMARKS

I. Preliminary Remarks

No claims have been amended. Claim 1 has been canceled. Claims 45-62 have been added. Claims 45-62 remain in the application. Early and favorable consideration of the application, as amended, are respectfully requested.

The present application is a continuation of co-pending U.S. application Serial No. 08/072,162, filed November 18, 1996, which is itself a continuation of U.S. application Serial No. 08/137,672, filed October 15, 1993, now abandoned. Applicant respectfully submits that the effective filing date of the present application, and each of the claims therein, is October 15, 1993.

II. Identification of Patent Under 37 C.F.R. § 1.607(a)(1)

Applicant hereby requests that an interference be declared between the present application and U.S. Patent No. 6,012,457 to Lesh ("the Lesh '457 patent"), which issued on January 11, 2000.[1] The Lesh '457 patent is based on an application filed July 8, 1997, and includes claims 1-32. Claim 1 is an independent claim. The remaining claims depend either directly or indirectly from independent claim 1.

As illustrated in the following table, claims 1, 3-5, 8, 11, 16, 24 and 29-32 have been copied from the Lesh '457 patent as new claims 51-62.

Lesh '457 Patent-Present Application	Lesh '457 Patent-Present Application
1 - 51	16 - 57
3 - 52	24 - 58
4 - 53	29 - 59
5 - 54	30 - 60
8 - 55	31 - 61
11 - 56	32 - 62

[1] A copy of the Lesh '457 patent is attached hereto as Exhibit 1.

As the effective filing date of the Lesh '457 patent is later than the effective filing date of the present application, it is respectfully submitted that applicant is the prospective senior party and that a statement or *prima facia* showing under 37 C.F.R. § 1.608 is not required.

III. Presentation of Proposed Count Under 37 C.F.R. § 1.607(a)(2)

Applicant hereby proposes the following count:

> A method of forming a lesion in a left atrium of a patient, comprising the steps of:
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> introducing a circumferential ablation device including an expandable member and a circumferential ablation element into the left atrium;
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> expanding the expandable member;
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> engaging a circumferential region of tissue at a location where a pulmonary vein extends from the left atrium with the circumferential ablation device; and
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> ablating the circumferential region of tissue with the circumferential ablation element.

IV. Identification of Claims in the Lesh '457 Patent Corresponding the Proposed Count Under 37 C.F.R. § 1.607(a)(3)

For the reasons presented below, applicant respectfully submits that claims 1-16 and 18-32 of the Lesh '457 patent correspond to the proposed count.

A. Independent claim 1 of the Lesh '457 Patent

Referring first to the preambles, claim 1 of the Lesh '457 patent is directed to a "method for treating a left atrial arrhythmia in a left atrium of a patient." The arrhythmia is treated by ablating tissue in the left atrium. [See clause 4 of claim 1.] The count is directed to a "method of forming a lesion in a left atrium of a patient." The lesion is formed in the left atrium by ablating tissue. [See clause 4 of the count.] As such, the preamble of claim 1 and the preamble of the count call for methods having the same end result -- the formation of a lesion in the left atrium of a patient.

The first clause in claim 1 of the Lesh '457 patent calls for the step of "introducing a circumferential ablation member into the left atrium ... comprising an expandable member and an ablation element." The last clause in claim 1 refers to "the ablation element" recited in the first clause as "*the circumferential* ablation element." Applicant respectfully submits, therefore, that the relevant portion of the first clause of claim 1 should be read as calling for a "circumferential ablation element." The first clause of the count calls for the step of "introducing a circumferential ablation device including an expandable member and a circumferential ablation element into the left atrium." Thus, but for slightly different terminology, the first clause of claim 1 and the first clause of the count recite the same method step -- the step of inserting a device into the left atrium that includes and expandable member and a circumferential ablation element.

The second and third clauses in claim 1 of the Lesh '457 patent call for the steps of "positioning the circumferential ablation member along a location where a pulmonary vein extends from the left atrium" and "expanding the expandable member until the expandable member engages a circumferential region of tissue along the location." With respect to the interpretation of the third clause, claim 8 of the Lesh '457 patent, which depends from independent claim 1, states that tissue is engaged by expanding the expandable member and advancing the expanded expandable member until it engages tissue. Alternatively, claim 26, which also depends from claim 1, states that tissue is engaged by expanding the expandable member from a collapsed position to

an expanded position that engages the tissue. Applicant respectfully submits, therefore, that the third clause of claim 1 is necessarily broad enough to encompass both expanding an expandable member and then advancing it into tissue (claim 8) and expanding an expandable member directly into the tissue (claim 26).

With respect to the count, clauses two and three of the count call for the steps of "expanding the expandable member" and "engaging a circumferential region of tissue at a location where a pulmonary vein extends from the left atrium with the circumferential ablation device." When viewed in their totality, clauses two and three of claim 1 and clauses two and three of the count call for the same method steps -- the steps of expanding a circumferential ablation device and engaging a circumferential region of tissue at a location where the pulmonary vein extends from the left atrium.

The fourth clause in claim 1 of the Lesh '457 patent calls for the step of "ablating the circumferential region of tissue with the circumferential ablation element while the expandable member is expanded and engaged to the circumferential region of tissue." The fourth clause of the count calls for "ablating the circumferential region of tissue with the circumferential ablation element." Given that clauses two and three of the count recite "expanding the expandable member" and "engaging a circumferential region of tissue," the lack of a re-recitation of these limitations in clause four does not differentiate the count from claim 1. Clause four of claim 1 and clause four of the count are, therefore, directed to the same step -- the step of ablating a circumferential region of tissue with a circumferential ablation element that is on an expanded expandable member.

In view of the forgoing, applicant respectfully submits that claim 1 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

B. Dependent claims 2 and 3 of the Lesh '457 Patent

Claims 2 and 3 of the Lesh '457 patent each depend from independent claim 1 and stipulate that "the left atrial arrhythmia originates at least in part from an

arrhythmogenic origin located along the pulmonary vein." In addition to the steps recited in claim 1, claim 2 specifies that the tissue being ablated is "the circumferential region of tissue at the location which includes the arrhythmogenic origin," while claim 3 specifies that the tissue being ablated is "at the location which is between the arrhythmogenic origin and the left atrium, such that the left atrium is electrically isolated from the arrhythmogenic origin."

Although the count does not require the specific ablation locations recited in claims 2 and 3, the ablation of tissue at the claimed locations was well known prior in the art to the filing date of the Lesh '457 patent. With respect to claim 2, U.S. Patent No. 5,334,193 to Nardella ("the Nardella '193 patent"),[2] which is prior art with respect to the Lesh '457 patent, discloses the ablation of tissue at an arrhythmogenic origin. [Column 1, lines 48-62.] Turning to claim 3, U.S. Patent No. 5,545,193 to Fleischman ("the Fleischman '193 patent"),[3] which is also prior art with respect to the Lesh '457 patent, discloses the ablation of a circumferential region of tissue between the left atrium and the pulmonary vein. [Column 6, line 56 to column 7, line 25.] The circumferential region would necessarily be located between the left atrium and an arrhythmogenic origin located along the pulmonary vein. Accordingly, to the extent that there are any substantive differences between the count and claims 2 and 3 of the Lesh '457 patent, the differences are such that the subject matter of claims 2 and 3 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claims 2 and 3 of the Lesh '457 patent are directed to the same patentable invention as the count and, therefore, correspond to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

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[2] A copy of the Nardella '193 patent is attached hereto as Exhibit 2.

[3] A copy of the Fleischman '193 patent is attached hereto as Exhibit 3.

C. Dependent claim 4 of the Lesh '457 Patent

Claim 4 of the Lesh '457 patent depends from independent claim 1 and specifies that "the circumferential lesion has a lesion width [that] is less than two-thirds the lesion circumference."

Although the count does not require the specific lesion dimensions recited in claim 4, the formation of long, thin lesions was well known in the art prior to the filing date of the Lesh '457 patent. For example, the Fleischman '193 patent discloses a method of forming long, thin lesions in a maze pattern to cure atrial fibrillation. The method includes the step of forming a lesion around a pulmonary vein with a relatively thin, hoop-shaped ablating element 42(6). [Figure 13, column 7, lines 1-23 and column 20, lines 25-54.] The hoop-shaped ablating element 42(6) would inherently form a circumferential lesion with a width that is less than two-thirds of the lesion circumference. Accordingly, to the extent that there are any substantive differences between the count and claim 4 of the Lesh '457 patent, the differences are such that the subject matter of claim 4 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 4 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

D. Dependent claim 5 of the Lesh '457 Patent

Claim 5 of the Lesh '457 patent depends from independent claim 1 and specifies that "the circumferential region of tissue at the location which includes the pulmonary vein ostium" is ablated. Similarly, the count calls for the steps of "engaging a circumferential region of tissue at a location where a pulmonary vein extends from the left atrium with the circumferential ablation device" and "ablating the circumferential region of tissue with the circumferential ablation element." Given the fact that the pulmonary vein ostium is the entrance into the pulmonary vein (i.e. the location where

the pulmonary vein extends from the left atrium), applicant respectfully submits that claim 5 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

E. Dependent claims 6 and 7 of the Lesh '457 Patent

Claim 6 of the Lesh '457 patent depends from independent claim 1. In addition to the steps recited in claim 1, claim 6 adds the steps of "monitoring electrical conduction signals along the pulmonary vein" and "identifying an origin of atrial arrhythmia as being located in the pulmonary vein based upon the monitored electrical conduction signals." Claim 7 depends from claim 6 and adds the step of "selecting the location at a position between the identified origin of atrial arrhythmia and the left atrium." Applicant notes that the "location," as defined by claim 1, is the "location where a pulmonary vein extends from the left atrium."

Although the count lacks the "monitoring," "identifying," and "selecting" steps recited in claims 6 and 7, such steps were well known in the art prior to the filing date of the Lesh '457 patent. For example, U.S. Patent No. 5,938,660 to Swartz ("the Swartz '660 patent"),[4] which is based on an application filed prior to the application that matured into the Lesh '475 patent and is therefore prior art with respect to the Lesh '457 patent, teaches the "monitoring," "identifying," and "selecting" steps as part of a method of forming a circumferential lesion around a pulmonary vein to cure arrhythmia. [Column 10, lines 2-12.] Accordingly, to the extent that there are any substantive differences between the count and claims 6 and 7 of the Lesh '457 patent, the differences are such that the subject matter of claims 6 and 7 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claims 6 and 7 of the Lesh '457 patent are directed to the same patentable invention as the count and, therefore, correspond to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

F. Dependent claim 8 of the Lesh '457 Patent

Claim 8 of the Lesh '457 patent depends from independent claim 1 and specifies that the circumferential region of tissue is engaged by "expanding the expandable member from a radially collapsed position to a radially expanded position while the expandable member is positioned within the left atrium" and "advancing the expandable member when in the radially expanded position toward the pulmonary vein until the expandable member engages the pulmonary vein wall."

The count does not specifically require the expandable member to be advanced into tissue after being expanded. The count simply calls for the steps of "expanding the expandable member" and "engaging a circumferential region of tissue." However, in order to engage tissue during performance of the method defined by the count, the expandable member must be either be (1) expanded within the atrium and then advanced toward the tissue until the tissue is engaged, or (2) located adjacent to the tissue such that it will engage the tissue when it expands and then expanded until it engages the tissue. Either technique would have been obvious in view of the count. The Fleischman '193 patent, for example, discloses both techniques. With respect to the first technique (i.e. the technique required by claim 8),[5] the Fleischman '193 patent discloses the use of a hoop-shaped ablating element 42(6) to form a lesion around a pulmonary vein. The ablating element 42(6) is deployed within the atrium and then advanced into tissue associated with the pulmonary vein. [Figure 13 and column 20, lines 28-37 and 49-54.] Accordingly, to the extent that there are any substantive differences between the count and claim 8 of the Lesh '457 patent, the differences are such that the subject matter of claim 8 would have been obvious over the count to one having ordinary skill in the art.

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[4] A copy of the Swartz '660 patent is attached hereto as Exhibit 4.

[5] The second technique is discussed below with respect to claim 26.

In view of the forgoing, applicant respectfully submits that claim 8 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

G. Dependent claim 9 of the Lesh '457 Patent

Claim 9 of the Lesh '457 patent depends from independent claim 1 and specifies that the expandable member "comprises a balloon which is fluidly coupled to a pressurizeable fluid source." In addition to the steps recited in claim 1, claim 9 includes the step of "expanding the balloon to a radially expanded position by pressurizing the balloon with fluid from the pressurizeable fluid source." The count does not specifically require the balloon or the "pressurizing" step and, instead, includes the broader recitations of "an expandable member" and the step of "expanding the expandable member."

Nevertheless, the use of a balloon coupled to a pressurizeable fluid source and the step of expanding the balloon with fluid from the source were well known in the art prior to the filing date of the Lesh '457 patent. For example, the Fleischman '193 patent discloses a circumferential ablation device 42(7) that consists of a conducting region 104 and an expandable balloon 166 that is connected to a source of pressurized fluid. [Figure 14 and column 20, line 58 to column 21, line 44.] The Fleischman '193 patent also discloses the step of expanding the balloon 166 by pressurizing the balloon with fluid from the source. [Column 21, lines 41-60.] Accordingly, to the extent that there are any substantive differences between the count and claim 9 of the Lesh '457 patent, the differences are such that the subject matter of claim 9 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 9 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

H. Dependent claim 10 of the Lesh '457 Patent

Claim 10 of the Lesh '457 patent depends from claim 1 and specifies that "the circumferential lesion has a lesion width which is less than two-thirds of a working length of the expandable member." Although the count calls for the broader step of "ablating the circumferential region of tissue with the circumferential ablation element," the claimed step was well known in the art prior to the filing date of the Lesh '457 patent.

The Swartz '660 patent, for example, teaches the use of a circumferential pulmonary vein ablation device that would appear to create lesion that is less than two-thirds the working length of the expandable member, i.e. less than two-thirds of region including the inflatable balloons 20 and 22 and the circumferential electrode 30. [Note Figure 7.] The Fleischman '193 patent discloses the use of an expandable balloon 166 with a conducting region 104 extending around the balloon and non-conducting regions 106 on either side of the conducting region. [Figure 14 and column 20, lines 58-67.] The width of a lesion created by the conducting region 104 would clearly be less than two-thirds of the working length of the balloon 166. Accordingly, to the extent that there are any substantive differences between the count and claim 10 of the Lesh '457 patent, the differences are such that the subject matter of claim 10 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 10 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

I. Dependent claim 11 of the Lesh '457 Patent

Claim 11 of the Lesh '457 patent depends from independent claim 1 and specifies that "antegrade blood flow [is allowed] to perfuse from the pulmonary vein and into the left atrium through the location when engaging the expandable member with

the circumferential region of tissue ... while ablating the circumferential region of tissue with the circumferential ablation element."

Although the count calls for the broader step of "ablating the circumferential region of tissue with the circumferential ablation element," allowing blood to flow in the manner defined by claim 11 was well known in the art prior to the filing date of the Lesh '457 patent. The Fleischman '193 patent, for example, discloses the formation of a circumferential lesion around a pulmonary vein with a hoop-shaped ablating element 42(6). [Figure 13.] Blood would necessarily flow through the hoop-shaped ablating element 42(6) during an ablation procedure. Accordingly, to the extent that there are any substantive differences between the count and claim 11 of the Lesh '457 patent, the differences are such that the subject matter of claim 11 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 11 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

J. Dependent claims 12-15 of the Lesh '457 Patent

Claim 12 of the Lesh '457 patent depends from independent claim 1 and claims 13-15 depend from claim 12. In addition to the steps recited in claim 1, claim 12 adds the steps of "providing a plurality of circumferential ablation device assemblies ... with a different expanded outer diameter than the other expandable members," "measuring an inner diameter along the location" and "selecting one of the circumferential ablation device assemblies for ablating the circumferential region of tissue based upon ... the measured inner diameter." Claim 13 specifies that it is the "pulmonary vein ostium" that is measured and claims 14 and 15 respectively call for x-ray and ultrasonic imaging measurement techniques. The count does not require such steps.

Applicant respectfully submits that the steps of providing differently sized expandable devices and measuring a region of the heart prior to using the expandable devices were well known in the art prior to the filing date of the Lesh '457 patent. For

example, U.S. Patent No. 5,702,368 to Stevens ("the Stevens '368 patent"),[6] which is prior art with respect to the Lesh '457 patent, discloses the steps of providing differently sized versions of balloon 227 for different patients and measuring the appropriate region of the heart. [Figure 16 and column 24, line 57 to column 25, line 8.] The Stevens '368 patent also discloses that the devices disclosed therein may be used in ablation procedures. [Column 20, lines 40-45.] With respect to claim 13, given the fact that the lesion in the method defined by the count is being formed where the pulmonary vein extends from the left atrium, one of skill in the art would have readily recognized that the pulmonary vein ostium is the location that would be measured. With respect to claims 14 and 15, the use of x-ray and ultrasonic measurement techniques were well known in the art prior to the filing date of the Lesh '457 patent. The Stevens '368 patent, for example, discloses such techniques. [Column 25, lines 5-8.] Accordingly, to the extent that there are any substantive differences between the count and claims 12-15 of the Lesh '457 patent, the differences are such that the subject matter of claims 12-15 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claims 12-15 of the Lesh '457 patent are directed to the same patentable invention as the count and, therefore, correspond to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

K. Dependent claims 16 and 18 of the Lesh '457 Patent

Claims 16 and 18 of the Lesh '457 patent each depend from independent claim 1. In addition to the steps recited in claim 1, claim 16 adds the step of "ablating an elongate region of tissue located along a left atrial wall of the left atrium with a linear lesion ablation element provided along a linear lesion ablation member." In addition to the steps recited in claim 1, claim 18 adds the steps of "forming a circumferential lesion by ablating the circumferential region of tissue" and "forming a linear lesion by ablating the elongate region of tissue, wherein the circumferential lesion and the linear lesion are formed such that they intersect."

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[6] A copy of the Stevens '368 patent is attached hereto as Exhibit 5.

Although the count does not require such steps, the steps were well know prior to the filing date of the Lesh '457 patent. The Fleischman '193 patent, for example, discloses the formation of a lesion pattern including a lesion around a pulmonary vein and a linear lesion intersecting the lesion formed around the pulmonary vein. [Figure 2 and column 6, line 56 to column 7, line 25.] The circumferential lesion around the pulmonary vein may be formed with the hoop-shaped ablating element 42(6) illustrated in Figure 13. [Column 20, lines 25-54.] The Fleischman '193 patent also discloses the step of forming linear lesions by ablating tissue with a linear ablating element 176 after a circumferential lesion has been formed and that the linear lesions can be used to complete the lesion pattern started with the hoop-shaped ablating element 42(6). [Column 22, lines 50-59 and column 23, lines 38-41.] Accordingly, to the extent that there are any substantive differences between the count and claims 16 and 18 of the Lesh '457 patent, the differences are such that the subject matter of claims 16 and 18 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claims 16 and 18 of the Lesh '457 patent are directed to the same patentable invention as the count and, therefore, correspond to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

L. Dependent claims 19-21 of the Lesh '457 Patent

Dependent claim 19 depends from independent claim 1. In addition to the steps recited in claim 1, claim 19 adds the steps of "advancing a guidewire from the left atrium and into the pulmonary vein" and "tracking a guidewire tracking member coupled to the circumferential ablation member over the guidewire until the circumferential ablation member is positioned along the location." Although the count does not require the additional steps recited in claim 19, the steps were well know prior to the filing date of the Lesh '457 patent. For example, the step of advancing a guidewire from the left atrium into a pulmonary vein when creating lesions within the left atrium is disclosed in

U.S. Patent No. 5,687,723 to Avitall ("the Avitall '723 patent"),[7] which is prior art with respect to the Lesh '457 patent. [Figures 14, 15a and 15b and column 9, lines 34-57.[8]] The step of tracking a guidewire tracking member over a guide wire is also disclosed. [Figure 8 and column 7, lines 35-47.]

Dependent claim 20, which depends from claim 19, requires that the tracking member form a bore located between a distal guidewire port and a proximal guidewire port located proximally of the distal guidewire port. Claim 20 also adds the step of "coupling the guidewire with the guidewire tracking member by engaging the guidewire within the bore through the distal and proximal guidewire ports." Although the count does not require the structural limitation and additional step recited in claim 20, the structural limitation and step were well know prior to the filing date of the Lesh '457 patent. For example, the Avitall '723 patent discloses a bore with proximal and distal guidewire ports and the step of engaging the guidewire with the bore through the proximal and distal ports. [Note rider segment 144 in Figure 8.] U.S. Patent No. 5,522,818 to Keith ("the Keith '818 patent"),[9] which is prior art with respect to the Lesh '457 patent, discloses a catheter having a distal balloon 26 and a guidewire lumen 52. [Figure 4 and column 5, line 53 to column 6, line 11.] The guidewire lumen 52 has a port proximal of the balloon 26 and a port distal of the balloon 26.

Dependent claim 21, which depends from claim 20, adds the step of "positioning the guidewire at least in part within the pulmonary vein before coupling the guidewire with the guidewire tracking member." Although the count does not require the additional step recited in claim 21, the step was well know prior to the filing date of the Lesh '457 patent. For example, the Avitall '723 patent discloses advancing a catheter over a guidewire after the guidewire has reached its target location and that target may be the pulmonary vein. [Column 8, lines 17-24 and column 9, lines 34-57.]

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[7] A copy of the Avitall '723 patent is attached hereto as Exhibit 6.

[8] It should be noted that this portion of the Avitall specification includes typographical errors in that the first digit of each of the reference numerals should be a "3," as shown in Figures 14, 15a and 15b, as opposed to a "1," as recited in the text. For example, reference numeral "140" in the text should be "340," as shown in the drawings.

Accordingly, to the extent that there are any substantive differences between the count and claims 19-21 of the Lesh '457 patent, the differences are such that the subject matter of claims 19-21 would have been obvious over the count to one having ordinary skill in the art, is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

M. Dependent claims 22 and 23 of the Lesh '457 Patent

Dependent claim 22 depends from independent claim 1. In addition to the limitations of claim 1, claim 22 states that the "ablation element is located at least in part within and is at least in part surrounded by the expandable member." Claim 23 also requires that the step of ablating the circumferential region of tissue be done by "ablatively coupling the circumferential ablation element with the circumferential region of tissue through the expandable member." Dependent claim 23 depends from claim 22 and adds the steps of "contacting the circumferential region of tissue with the wall when the expandable member is expanded" and "ablating the circumferential region of tissue by ablatively coupling the circumferential ablation element with the circumferential region of tissue through the wall of the expandable member."

Although the count does not require the claimed structural limitation and steps, the structural limitation and steps were well know prior to the filing date of the Lesh '457 patent. For example, U.S. Patent No. 5,879,348 to Owens ("the Owens '348 patent"),[10] which is prior art with respect to the Lesh '457 patent, discloses the use of an expandable body with an electrode located therein and the step of coupling the electrode to tissue through the expandable body, when expanded, to ablate tissue within the heart. [Figures 2-4 and column 5, line 17 to column 6, line 41.] Accordingly, to the extent that there are any substantive differences between the count and claims 22 and 23 of the Lesh '457 patent, the differences are such that the subject matter of

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[9] A copy of the Keith '818 patent is attached hereto as Exhibit 7.

[10] A copy of the Owens '348 patent is attached hereto as Exhibit 8.

claims 22 and 23 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claims 22 and 23 of the Lesh '457 patent are directed to the same patentable invention as the count and, therefore, correspond to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

N. Dependent claim 24 of the Lesh '457 Patent

Dependent claim 24 depends from independent claim 1. In addition to the limitations of claim 1, claim 24 states that the "expandable member comprises an outer surface and the ablation element is located at least in part along the outer surface." Claim 24 also adds the steps of "contacting at least a portion of the circumferential region of tissue with the ablation element when the expandable member is expanded" and "ablating the circumferential region of tissue with the ablation element while the ablation element is in contact with at least the portion of the circumferential region of tissue."

The count does not require the claimed structural limitation and steps. Nevertheless, the structural limitation and steps were well know prior to the filing date of the Lesh '457 patent. For example, the Fleischman '193 patent discloses an ablation element 42(6) consisting of an expandable member 162 and one or more conducting regions 104 located on the outer surface of the expandable member. [Figure 13 and column 20, lines 42-48.] The Fleischman '193 patent also discloses the steps of contacting a circumferential region of tissue with ablation elements and ablating tissue when the conducting regions 104 are in contact with tissue. [Figure 13, column 7, lines 62-65 and column 11, lines 29-31.] Accordingly, to the extent that there are any substantive differences between the count and claim 24 of the Lesh '457 patent, the differences are such that the subject matter of claim 24 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 24 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

O. Dependent claim 25 of the Lesh '457 Patent

Dependent claim 25 depends from independent claim 1. In addition to the limitations of claim 1, claim 25 states that the "expandable member comprises first and second end portions and an intermediate region therebetween." Claim 25 also adds the steps of "engaging the first and second end portions with first and second adjacent regions of tissue, respectively, located on opposite sides of the circumferential region of tissue while engaging only the intermediate region with the circumferential region of tissue" and "ablatively coupling the circumferential ablation element to only a circumferential area that surrounds the intermediate region such that only the circumferential region of tissue is ablated when the intermediate region is engaged to the circumferential region of tissue and the first and second end portions are respectively engaged with the first and second adjacent regions of tissue."

Although the count does not require the claimed structural limitation and steps, the structural limitation and steps were well know prior to the filing date of the Lesh '457 patent. For example, the Fleischman '193 patent discloses a circumferential ablation device 42(7) that consists of an expandable balloon 166, a conducting region 104 extending around the balloon, and non-conducting regions 106 on either side of the conducting region. [Figure 14 and column 20, lines 58-67.] The Fleischman '193 patent also discloses the steps of engaging the non-conducting regions 106 with tissue on opposite sides of the tissue engaged by the conducting region 104 and ablating only the area in contact with the circumferential region. [Column 21, lines 56-60.] Accordingly, to the extent that there are any substantive differences between the count and claim 25 of the Lesh '457 patent, the differences are such that the subject matter of claim 25 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 25 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

P. Dependent claim 26 of the Lesh '457 Patent

Dependent claim 26 depends from independent claim 1 and requires that the expandable member be engaged with the circumferential region of tissue "by positioning the expandable member along the location in a radially collapsed position and then expanding the expandable member from the radially collapsed condition to a radially expanded position which engages the circumferential region of tissue."

The count does not specifically require the expandable member to be expanded into a position that engages the tissue. The count simply calls for the steps of "expanding the expandable member" and "engaging a circumferential region of tissue." However, in order to engage tissue during performance of the method defined by the count, the expandable member must be either be (1) expanded within the atrium and then advanced toward the tissue until the tissue is engaged, or (2) located adjacent to the tissue such that it will engage the tissue when it expands and then expanded until it engages the tissue. Either technique would have been obvious in view of the count. The Fleischman '193 patent, for example, discloses both techniques. With respect to the second technique (i.e. the technique recited in claim 26),[11] the Fleischman '193 patent discloses an inflatable ablating element 42(7) that is deployed within the atrium and then expanded until it engages tissue. [Figure 14 and column 21, lines 25-60.] In addition, the Swartz '660 patent discloses a device 10 that is used to form lesions around the pulmonary vein including a pair of inflatable balloons 20 and 22. The balloons 20 and 22 are inflated into engagement with tissue after the device has been positioned within a pulmonary vein. Accordingly, to the extent that there are any substantive differences between the count and claim 26 of the Lesh '457 patent, the

[11] The first technique is discussed above with respect to claim 8.

differences are such that the subject matter of claim 26 would have been obvious over the count to one having ordinary skill in the art.

In view of the forgoing, applicant respectfully submits that claim 26 of the Lesh '457 patent is directed to the same patentable invention as the count and, therefore, corresponds to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

Q. Claims 27-32 of the Lesh '457 Patent

Dependent claims 27-32 each depend from independent claim 1 and call for the step of ablating the circumferential region of tissue to be performed using specific ablation techniques. The techniques include ultrasound ablation (claim 27), thermal ablation (claim 28), cryogenic ablation (claim 29), ablative fluid ablation (claim 30), microwave ablation (claim 31) and optical ablation (claim 32).

Although the count does not require the specific ablation techniques recited in claims 27-32, such techniques were well know prior to the filing date of the Lesh '457 patent. For example, U.S. Patent No. 5,630,837 to Crowley ("the Crowley '837 patent"),[12] which is prior art with respect to the Lesh '457 patent, is directed to ultrasound-based ablation devices for treating arrhythmias. U.S. Patent No. 5,571,088 to Lennox ("the Lennox '088 patent"),[13] which is prior art with respect to the Lesh '457 patent, discloses the use of an expandable balloon 22 to thermally ablate tissue within the heart. [Figure 1 and column 4, lines 8-59.] The Fleischman '193 patent discloses that ablation by cooling, ablative fluid ablation, microwave ablation and optical ablation techniques may be used in combination with a device that creates circumferential lesions. [Column 7, lines 39-65.] Accordingly, to the extent that there are any substantive differences between the count and claims 27-32 of the Lesh '457 patent, the differences are such that the subject matter of claims 27-32 would have been obvious over the count to one having ordinary skill in the art.

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[12] A copy of the Crowley '837 patent is attached hereto as Exhibit 9.
[13] A copy of the Lennox '088 patent is attached hereto as Exhibit 10.

In view of the forgoing, applicant respectfully submits that claims 27-32 of the Lesh '457 patent are directed to the same patentable invention as the count and, therefore, correspond to the count in accordance with 37 C.F.R. §§ 1.601(n) and 1.606.

V. Presentation of Claims Corresponding the Proposed Count Under 37 C.F.R. § 1.607(a)(4)

Claims 45-62 are pending in the present application. For the reasons presented below, applicant respectfully submits that clams 45, 50, 51 and 54 correspond to the count and that claims 46-49, 52, 53 and 55-62 do not correspond to the count.

A. Claims 45-50

Independent claim 45 is identical to the count. As such, applicant respectfully submits that claim 45 corresponds exactly to the count.

Claims 46-49 (which depend from claim 45) differ substantially from the count and the differences are such that their subject matter as a whole would not have been obvious at the time applicant's invention was made to a person having ordinary skill in the art. As such, applicant respectfully submits that claims 46-49 do not correspond to the count.

Claim 50 (which depends from claim 45) differs from the count in that it requires the "ablating" step to comprise "transmitting energy into the tissue." The transmission of energy into tissue was a well known ablation technique and would have been an obvious modification of the invention defined by the count at the time applicant's invention was made. As such, applicant respectfully submits that claim 50 corresponds to the count.

B. Claims 51-62

Independent claim 51 is identical to claim 1 of the Lesh '457 patent. Applicant respectfully submits that claim 51 corresponds to the count for the reasons discussed in Section IV-A with respect to claim 1 of the Lesh '457 patent.

Claim 54 (which depends from claim 51) is identical to claim 5 of the Lesh '457 patent. Applicant respectfully submits that claim 54 corresponds to the count for the reasons discussed in Section IV-D with respect to claim 5 of the Lesh '457 patent.

Claims 52, 53 and 55-62 (which depend from claim 51) differ substantially from the count and the differences are such that their subject matter as a whole would not have been obvious at the time applicant's invention was made to a person having ordinary skill in the art. As such, applicant respectfully submits that claims 52, 53 and 55-62 do not correspond to the count.

The great disparity in the effective filing dates of the present application (October 15, 1993) and the Lesh '457 patent (July 8, 1997) leads to the following situation: despite the fact that claims 3, 4, 8, 11, 16, 24 and 29-32 of the Lesh '457 patent are identical to claims 52, 53 and 55-62 of the present application, claims 3, 4, 8, 11, 16, 24 and 29-32 of the Lesh '457 patent should at least be initially designated as correspond to the count, while claims 52, 53 and 55-62 of the present application should not. As illustrated below, the applicable law and Patent Office rules necessitate such initial designations and will ultimately resolve any issues raised thereby.

Claims correspond to a count if they "define the same patentable invention as the count." [37 C.F.R. § 1.606.] C.F.R. § 1.601(n) states that "[i]nvention 'A' is the *same patentable invention* as invention 'B' when invention 'A' is the same as (35 U.S.C. 102) or obvious over (35 U.S.C. 103) invention 'B' assuming invention 'B' is prior art with respect to invention 'A'." Thus, a claim corresponds to the count if the claim is the same as the count, as defined by 35 U.S.C. § 102, or is obvious over the count, as defined by 35 U.S.C. § 103, assuming that the count is prior art. [*See also* M.P.E.P. § 2309.2.] Obviousness under 35 U.S.C. § 103 is determined by comparing the claimed invention to the prior art "at the time the invention was made" and, absent evidence to the contrary,

the date of invention is presumed to be the filing date of the application. [37 C.F.R. § 1.657(a).]

Applying the law and rules to the present situation, claims 3, 4, 8, 11, 16, 24 and 29-32 of the Lesh '457 patent must be compared to the count and any prior art that existed as of the filing date of the Lesh application (July 8, 1997), while claims 52, 53 and 55-62 of the present application must be compared to the count and any prior art that existed as of the effective filing date of the present application (October 15, 1993). The prior art "teaching" references that have been applied to claims 3, 4, 8, 11, 16, 24 and 29-32 of the Lesh '457 patent in the 35 U.S.C. § 103 obviousness analysis under C.F.R. §§ 1.606 and 1.601(n)[14] are not prior art with respect to claims 52, 53 and 55-62 of the present application and cannot be applied to claims 52, 53 and 55-62 in the obviousness analysis. Absent the existence of other "teaching" references that are in fact prior art, there is no evidence that, at the time the inventions defined by claims 52, 53 and 55-62 were made, the claims were obvious over the count. Without such evidence of obviousness, claims 52, 53 and 55-62 simply cannot correspond to the count.

Interference procedures after the initial designation of claims corresponding to the count will ultimately resolve any issues associated with this situation in a logical and expected manner. If, for example, Lesh can prove that the "teaching" references are not prior art,[15] then Lesh will be able to move under 37 C.F.R. § 1.633(c) to have some or all of claims 3, 4, 8, 11, 16, 24 and 29-32 of the Lesh '457 patent designated as not corresponding to the count. A similar motion under 37 C.F.R. § 1.633(c) could be made if Lesh can show that some or all of the claims are not obvious in view of the count even assuming that the "teaching" references are prior art. Nevertheless, given the fact that there would now be identical claims in the present application and Lesh '457 patent that did not correspond to the single proposed count, one or more counts would have to be added to the interference. Thereafter, the winning party would be entitled to the claims corresponding to the counts.

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[14] See Sections IV-B, C, F, I, K, N and Q above.

[15] Applicant notes, however, that all of the "teaching" references but one are prior art under 35 U.S.C. § 102(b).

If, on the other hand, Lesh is unable to prove that the "teaching" references are not prior art, then Lesh would also be unable to prove a date of invention that is prior to the filing date of the present application (which is earlier than the prior art dates of the "teaching" references). As such, Lesh would not be entitled to any claims that are identical to those of the present application no matter how many counts are ultimately required to define the interference. Applicant respectfully submits that this is precisely the result contemplated by the interference rules, which seek to resolve "all questions of entitlement to a patent" in the interference and to prevent additional *inter parte* proceedings concerning entitlement issues. [See the PTO response to comments regarding 37 C.F.R. § 601(n), 49 Fed. Reg. 48416.]

VI. Application of Claims Corresponding the Proposed Count Under 37 C.F.R. § 1.607(a)(5)

Applicant applies the claims corresponding to the count (claims 45, 50, 51 and 54) to the disclosure of the present application in the manner shown in the following table.[16] The claims that do not correspond to the count (claims 46-49, 52, 53 and 55-62) are also applied to the disclosure of the present application to assist the Examiner in his review thereof.

[16] References in the table to portions of the present application are merely examples of supporting disclosure and are not necessarily the sole supporting disclosure.

45. A method of forming a lesion in a left atrium of a patient, comprising the steps of:	The present application discloses a method of forming a lesion in the left atrium of a patient ("the disclosed method"). [Page 46, lines 26-30.]
introducing a circumferential ablation device including an expandable member and a circumferential ablation element into the left atrium;	The disclosed method includes the step of introducing an ablating element 42(6) into the left atrium 14. [Figure 13 and page 47, lines 11-16.] The ablating element 42(6) includes a hoop 162 that collapses and expands and a conducting region 104 that is used to ablate tissue. [Figure 13 and page 47, lines 3-7 and 11-14.]
expanding the expandable member;	The disclosed method includes the step of expanding the hoop 162. [Page 47, lines 11-14.]
engaging a circumferential region of tissue[17] *at a location where a pulmonary vein extends from the left atrium with the circumferential ablation device; and*	The disclosed method includes the step of engaging tissue associated with the pulmonary vein ostium (or "orifice") with the ablating element 42(6). [Page 18, lines 30-34 and page 46, lines 26-30.] The ablating element 42(6) will necessarily engage a circumferential region of tissue.
ablating the circumferential region of tissue with the circumferential ablation element.	The disclosed method includes the step of ablating the circumferential region of tissue with the conducting region 104. [Page 46, lines 26-30 and page 47, lines 11-16.]

[17] In the Comments On Statement Of Reasons For Allowance dated July 13, 1999, a copy of which is attached hereto as Exhibit 11, the patentee stated that the "circumferential region of tissue" includes tissue along the pulmonary vein and upstream of the pulmonary vein ostium, tissue along the pulmonary vein ostium, and tissue surrounding the pulmonary vein ostium. [Page 2, second paragraph, last sentence.] The Examiner's attention is also directed to Figures 7 and 8C of the Lesh '457 patent, which illustrate lesions formed in such tissue regions, and column 14, line 67 to column 15, line 6, which describes the formation of a lesion in the pulmonary vein ostium.

46. A method as claimed in claim 45, wherein the step of introducing a circumferential ablation device comprises introducing a circumferential ablation device including a collapsible/expandable hoop and a circumferential ablation element.	The ablating element 42(6) introduced in the disclosed method consists of a collapsible/expandable hoop 162 that carries a circumferential ablation element formed from either a continuous conductive region 104 or a series of conductive regions separated by non-conductive regions 106. [Page 46, line 33 to page 47, line 16.] The structure and formation of the conductive regions 104 and non-conductive regions 106 are described from page 26, line 31 to page 27, line 11.
47. A method as claimed in claim 45, wherein the step of introducing a circumferential ablation device comprises introducing a circumferential ablation device including a collapsible/expandable hoop and a continuous conductive region on the hoop.	The ablating element 42(6) introduced in the disclosed method consists of a collapsible/expandable hoop 162 that carries a continuous conductive region 104. [Page 46, line 33 to page 47, line 16.]
48. A method as claimed in claim 45, wherein the step of introducing a circumferential ablation device comprises introducing a circumferential ablation device including a collapsible/expandable hoop and a plurality of spaced conductive regions on the hoop.	The ablating element 42(6) introduced in the disclosed method consists of a collapsible/expandable hoop 162 that carries a series of conductive regions 104 separated by non-conductive regions 106. [Page 46, line 33 to page 47, line 16.]
49. A method as claimed in claim 45, wherein the step of engaging a circumferential region of tissue comprises encircling the pulmonary vein with the expandable member.	The disclosed method includes the step of encircling the pulmonary vein with the hoop 162. [Page 46, lines 26-30.]
50. A method as claimed in claim 45, wherein the step of ablating the circumferential region of tissue comprises transmitting energy into the tissue.	The disclosed method includes the step of transmitting energy into the tissue to ablate the tissue. [Page 18, lines 6-8 and page 47 lines 3-7.]

51. A method for treating a left atrial arrhythmia in a left atrium of a patient, comprising:	The disclosed method is directed to the formation of a lesion in the left atrium to treat arrhythmia. [Page 16, line 4 to page 17, line 6 and page 46, lines 26-30.]
introducing a circumferential ablation member into the left atrium, said circumferential ablation member comprising an expandable member and an ablation element;	The disclosed method includes the step of introducing an ablating element 42(6) into the left atrium 14. [Figure 13 and page 47, lines 11-16.] The ablating element 42(6) includes a hoop 162 that collapses and expands and a conducting region 104 that is used to ablate tissue. [Figure 13 and page 47, lines 3-7 and 11-14.]
positioning the circumferential ablation member along a location where a pulmonary vein extends from the left atrium;	The disclosed method includes the step of positioning the ablating element 42(6) at a location where the pulmonary vein extends from the left atrium. [Page 46, lines 26-30.]
expanding the expandable member until the expandable member engages a circumferential region of tissue[18] *along the location; and*	The disclosed method includes the step of expanding the ablating element 42(6) within the atrium to engage a circumferential region of tissue. [Page 18, lines 30-34, page 46, lines 26-30 and page 47, lines 11-16.]
ablating the circumferential region of tissue with the circumferential ablation element while the expandable member is expanded and engaged to the circumferential region of tissue.	The disclosed method includes the step of ablating the circumferential region of tissue while the ablating element 42(6) is expanded and engaged with tissue. [Page 18, lines 30-34, page 46, lines 26-30.]

[18] As discussed above in Section IV-A with respect to claim 1 of the Lesh '457 patent, which is identical to claim 51 of the present application, the phrase "expanding the expandable member until the expandable member engages a circumferential region of tissue" is necessarily broad enough to encompass both expanding an expandable member and then advancing it into tissue and expanding an expandable member directly into the tissue.

52. The method of claim 51, wherein the left atrial arrhythmia originates at least in part from an arrhythmogenic origin located along the pulmonary vein, and further comprising ablating the circumferential region of tissue at the location which is between the arrhythmogenic origin and the left atrium, such that the left atrium is electrically isolated from the arrhythmogenic origin.	The disclosed method would inherently include the step of ablating tissue between an arrhythmogenic origin located along the pulmonary vein and the left atrium in those instances when the arrhythmogenic origin happens to be located along the pulmonary vein. [Figure 2, page 16, lines 32-34.]

53. The method of claim 51, further comprising: forming a circumferential lesion by ablating the circumferential region of tissue such that the circumferential lesion has a lesion width and also a lesion circumference, wherein the lesion width is less than two-thirds the lesion circumference.	The disclosed method includes the step of forming a circumferential lesion with an ablating element 42(6). In the exemplary embodiment of the ablating element 42(6) illustrated in Figure 13, the width of the hoop 162 is a tiny fraction of the circumference. Even assuming *arguendo* that the ablating element 42(6) is not drawn to scale, such an ablating element would necessarily produce a lesion with a lesion width that is less than two-thirds of the lesion circumference.

54. The method of claim 51, further comprising ablating the circumferential region of tissue at the location which includes the pulmonary vein ostium.	The disclosed method includes the step of creating a lesion that encircles the orifice of the pulmonary vein (i.e. the "pulmonary vein ostium"). [Page 46, lines 26-30.]

55. The method of claim 51, further comprising engaging the expandable member with the circumferential region of tissue by: *expanding the expandable member from a radially collapsed position to a radially expanded position while the expandable member is positioned within the left atrium; and* *advancing the expandable member when in the radially expanded position toward the pulmonary vein until the expandable member engages the pulmonary vein wall.*	The disclosed method includes the step of expanding the hoop 162 from a collapsed position to an expanded position within the left atrium. [Page 47, lines 11-16.] As illustrated in Figure 13, the hoop 162 is in-plane with the catheter body. Assuming that the catheter body and hoop 162 are introduced into the left atrium in the manner illustrated in Figure 26, once expanded the hoop will have to be advanced forward until its distal end engages the atrial wall. From there, the hoop 162 will bend out of plane and around a pulmonary vein.[19]

56. The method of claim 51, further comprising: *allowing antegrade blood flow to perfuse from the pulmonary vein and into the left atrium through the location when engaging the expandable member with the circumferential region of tissue and also while ablating the circumferential region of tissue with the circumferential ablation element.*	The disclosed method employs a hoop-shaped ablating element 42(6) that, when positioned around a pulmonary vein during an ablation procedure, will necessarily allow antegrade blood flow. The present application also contemplates the presence of blood. [See the discussion concerning the ablating element illustrated in Figure 14 on page 49, lines 20-23.]

57. The method of claim 51, further comprising: *ablating an elongate region of tissue located along a left atrial wall of the left atrium with a linear lesion ablation element provided along a linear lesion ablation member.*	The disclosed method also includes the step of ablating an elongate region of tissue with a linear ablating element 176. [See Figures 27 and 28 and page 53, lines 5-17.]

[19] Applicant notes that if this were not the case, the hoop 162 have to expand directly into a position around a pulmonary vein in the manner defined by claim 26 of the Lesh '427 patent.

58. The method of claim 51, wherein the expandable member comprises an outer surface and the ablation element is located at least in part along the outer surface, and further comprising: *contacting at least a portion of the circumferential region of tissue with the ablation element when the expandable member is expanded;* *ablating the circumferential region of tissue with the ablation element while the ablation element is in contact with at least the portion of the circumferential region of tissue.*	The disclosed hoop 162 includes an outer surface and the conducting region 104 is located on the outer surface. [Page 26, line 31 to page 27, line 11.] The disclosed method includes the steps of contacting a circumferential region of tissue with the conducting region 104 when the hoop 162 is expanded and ablating the circumferential region of tissue with the conducting region when the conducting region is in contact with the circumferential region of tissue. [Page 46, line 23 to page 47, line 16.]

59. The method of claim 51, wherein the ablation element comprises a cryogenic ablation element, and further comprising: *ablating the circumferential region of tissue at least in part by activating the cryogenic ablation element to cool the circumferential region of tissue.*	The disclosed method includes the step of forming lesions by "destroying myocardial tissue by cooling." [Page 18, lines 20-23.] One of ordinary skill in the art would understand that "destroying myocardial tissue by cooling" is cryogenic ablation.

60. The method of claim 51, wherein the ablation element comprises a fluid delivery ablation element, and further comprising: *ablating the circumferential region of tissue at least in part by exposing an ablative fluid from the fluid delivery element to the circumferential region of tissue.*	The disclosed method includes the step of forming lesions by "injecting a chemical substance that destroys myocardial tissue." [Page 18, lines 20-23.] One of ordinary skill in the art would understand that the injected chemical substance would be an ablative fluid.

61. The method of claim 51, wherein the ablation element comprises a microwave ablation element, and further comprising: *ablating the circumferential region of tissue at least in part by inductively coupling the microwave ablation element with the circumferential region of tissue.*	The disclosed method includes the step of forming lesions with microwave energy. [Page 18, lines 8-10.]

62. The method of claim 51, wherein the ablation element comprises an optical ablation element, and further comprising: *ablating the circumferential region of tissue at least in part by optically coupling the optical ablation element with the circumferential region of tissue.*	The disclosed method includes the step of forming lesions with light energy. [Page 18, lines 8-10.]

VI. The Requirements of 35 U.S.C. § 135(b)

The Lesh '457 patent issued on January 11, 2000. As such, the claims presented under 37 C.F.R. § 1.607(a)(4) were made in the present application within a year of the issue date of the Lesh '457 patent and an explanation under 37 C.F.R. § 1.607(a)(6) is not required.

VII. Closing Remarks

Early and favorable consideration of the application, as amended, are respectfully requested. Allowance of the claims and a declaration of interference at an early date are courteously solicited.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to call applicant's undersigned representative at (310) 563-1458 to discuss the steps necessary for placing the application in condition for allowance.

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0638. Should such

fees be associated with an extension of time, applicant respectfully requests that this paper be considered a petition therefor.

Respectfully submitted,

2/6/00
Date

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